

## REMARKS

The Applicants note with appreciation the allowance of Claims 1, 5, 6, 10, 14-19, 23-28, 32-37, 50 and 53.

Claims 52 and 54-55 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. Specifically, the Official Action alleges that there is insufficient description of the full scope of nucleic acid sequences encoding cold-shock inducible genes, or genes regulated by elements other than those described in SEQ ID NOs: 49, 50, or the particularly recited portions of SEQ ID NO:55. The Official Action further asserts that, since there is no correlation between the structures of genes potentially regulated by these sequence elements, one skilled in the art must perform further experimentation to determine nucleic acid sequences that function as cold-shock inducible genes or genes that are regulated by the sequence elements recited in the rejected claims.

The Applicants respectfully submit that it is well known in the art to use a vector with regulatory sequence elements to control the expression of an inserted heterologous gene in a host organism. A heterologous gene is defined in the art as a gene originating from an organism of another species.

Claim 52 recites an expression vector that includes a heterologous gene specifically regulated by the sequence elements of SEQ ID NOs: 49, 50, or the particularly recited portions of SEQ ID NO: 55. Therefore, contrary to the suggestion in the Official Action, the claim is not drawn to a gene regulated by a mechanism other than the sequence elements of SEQ ID NOs: 49, 50, or the particularly recited portions of SEQ ID NO: 55.

Furthermore, Claim 52 does not recite any sequence encoding a cold-shock inducible gene or any gene regulated by cold-shock sequence elements, but rather pertains to the expression of a heterologous gene inserted into a vector. Simply by nature of being inserted into a vector containing the elements recited in Claim 50, the heterologous gene becomes a cold-shock inducible gene that is regulated by cold-shock sequence elements. Therefore, the structure of a gene potentially regulated by the cold-shock sequence elements is merely a matter of insertion of a heterologous gene into a vector that contains such regulatory elements. Indeed, the heterologous gene of the rejected claims may be derived from any organism other than *E. coli* and is not necessarily associated with cold-shock in its normal expression pattern.

As the Specification describes the regulatory sequence elements of SEQ ID NOs: 49, 50, or the particularly recited portions of SEQ ID NO: 55, one skilled in the art would fully appreciate that the Applicants were in possession of a vector expressing a heterologous gene under the control of these elements. Therefore, the Applicants respectfully submit that Claim 52 satisfies the written description requirement. Furthermore, as it is believed that the rejection of Claims 54 and 55 is due to dependence on rejected Claim 52, withdrawal of the rejection of Claims 52, and 54-55 under 35 U.S.C. §112, first paragraph is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is in condition for allowance, which is respectfully requested.

Respectfully submitted,



T. Daniel Christenbury  
Reg. No. 31,750  
Attorney to the Applicants

TDC/LML/vbm  
(215) 656-3381